

REMARKS

In the Office Action mailed March 6, 2008, the Examiner has noted an error in the identification of the priority document. The correct priority application is 60/372,617 and the correct priority date is April 11, 2002. To correct an inadvertent typographical error in the Declaration and Power of Attorney, submitted herewith is a first-filed Application Data Sheet captioned "Supplemental Application Data Sheet."

Claims 1-3 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description in the specification. The Examiner has alleged that the claims are drawn to a genus of peptides, and that the number of disclosed species is insufficient to support the genus, and further that the specification does not provide relevant identifying characteristics of the genus.

Applicants respectfully disagree. The written description requirement for a genus may be satisfied by a description of a representative number of species, reduction to drawings, or by disclosure of relevant identifying characteristics sufficient to show the applicant was in possession of the claimed genus. "Guidelines for Examination of Patent Applications under 35 U.S.C. §112, paragraph 1, "Written Description" Requirements," Fed. Reg. 66(4)1103, II, A.3.a(2) ("the Written Description Guidelines"). See, also, Example 5 of the USPTO training materials regarding examination under the written description requirement for partial protein structure.

Claim 1 recites a genus of peptides from five to fifteen amino acids in length and comprising the sequence EGGGE. The specification discloses three representative species (SEQ ID NOS: 1, 2 and 3) at page 7, lines 4-7. The specification and claims describe the core conserved region of the peptide (EGGGE). The specification describes methods of deriving the peptides from E-cadherin, VE-

cadherin, and N-cadherin. Specification at page 6, line 19 – page 8, line 14. The specification further describes relevant identifying characteristics including function, i.e., ability to bind to presenilin-1, correlated with structure, i.e., the conserved region of the peptide (EGGGE). Specification at page 6, line 19 – page 7, line 14. Accordingly, the written description requirement has been satisfied.

In the interest of advancing prosecution, Claim 1 has been amended to recite the function of the peptide, i.e., “that binds to presenilin-1.”

In view of the foregoing comments, withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Applicants note that the Office Action at page 6, first paragraph, refers to “antagonists of hedgehogs proteins” and assume that this paragraph was included in error. Clarification is requested.

Claims 1-3 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly vague and indefinite in the recitation “wherein the peptide is from 5 to 15 amino acids in length.” The Examiner has alleged that when the peptide comprises the 12-mer of SEQ ID NO:1, it is unclear what the other three amino acids are. Claim 1 has been amended to recite that the peptide binds to presenilin-1. Accordingly, the claims are clear and definite to one of ordinary skill in the art, who can determine amino acids that may be included in a 15-mer peptide comprising SEQ ID NO:1 such that the peptide binds the presenilin-1. Accordingly, withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-3 have been rejected under 35 U.S.C. §103(a) as allegedly rendered obvious by U. S. Patent No. 6,787,136 to Brenner et al. (“Brenner et al.”). The Examiner has alleged that Brenner et al. disclose a peptide having an amino acid sequence EEGGGEEDQD that reads on Claims 1 and 2.

Applicants respectfully disagree with the Examiner’s characterization of the teaching of Brenner et al. Brenner et al. simply do not teach a peptide having the

amino acid sequence EEGGGEEDQD. Rather, the disclosure of Brenner et al. is directed to the molecular cloning of the gene encoding synovial cadherin. The cloning method included extraction and reverse transcription of mRNA from rheumatoid synoviocytes, followed by PCR amplification of the resulting template. The PCR primers were designed by aligning the amino acid sequences of E-, P-, and N-cadherin and observing regions of identity. Four regions of identity were appreciated, including a region corresponding to human E-cadherin residues 753-762 (EEGGGEEDQD). Degenerate oligonucleotide primers were designed based upon these regions of identity. These steps were performed by examining strings of letters on paper or by computer. No peptides are isolated or synthesized, nor do Brenner et al. suggest making a peptide having a specific sequence. Further, Brenner et al. do not attribute any function or utility to any region of the sequence. Brenner et al. merely identify a region of a sequence by a sequence identification number; a peptide having that sequence is neither taught nor suggested.

The Examiner has further alleged that Brenner et al. disclose the amino acid sequence of a human cadherin-11 protein, and further discloses that unique fragments are those that retain a distinct functional capability of the polypeptide, and that a unique fragment will depend upon whether the fragment constitutes a portion of a conserved domain. Thus it would have been obvious to prepare the instantly claimed peptides, the Examiner has alleged.

Applicants disagree. Brenner et al. do not teach any specific peptides from the sequence of human cadherin-11, no less the peptides claimed herein that bind presenilin-1. Rather, Brenner et al. include vague, general language directed to so-called unique fragments of a 796 amino acid polypeptide. In particular, at Column 13, lines 8-10, Brenner et al. state that "[v]irtually any segment of SEQ ID NO:2 that is nine or more amino acids in length and which is not common to other distinct polypeptides will be unique." Brenner et al. thus contemplate hundreds of

thousands of fragments and provide no direction as to any particular fragment, nor any indication as to function of any fragment.

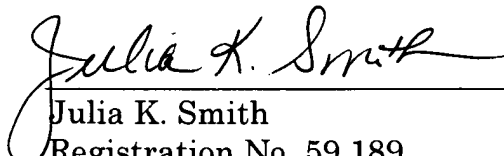
Further, Brenner et al. do not teach that a unique fragment of a cadherin-11 polypeptide will depend upon factors such as whether the fragment constitutes a portion of a conserved protein domain, as the Examiner has alleged. Rather, as discussed above, the reference teaches that virtually any segment of 9 or more amino acids is contemplated, and that the size of the fragment will depend upon factors such as whether the fragment constitutes a portion of a conserved protein domain. Brenner et al. at Column 12, line 67 – Column 13, line 3.

Accordingly, there is no rationale to motivate an ordinary skilled artisan to make the peptides of the claimed invention and no expectation of success in achieving the claimed peptides. A prima facie case of obviousness thus has not been established. Withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

In view of the foregoing comments and amendments, it is respectfully submitted that the present application is in condition for allowance. Favorable reconsideration and allowance of all pending claims is requested.

Respectfully submitted,

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Julia K. Smith
Registration No. 59,189
Janet M. MacLeod
Registration No. 35,263
Telephone: (212) 895-4206
Fax: (212) 223-4134

CROWELL & MORING LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
NYIWDMS: 10616272_1